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THE NEW LEGAL FRAMEWORK APPLICABLE TO MEDICAL DEVICES

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INTRODUCTION

A few years ago, many were shocked by the news that thousands of women across the world suffered harm caused by wrongly manufactured breast implants. For several years a French manufacturer had used industrial silicone instead of medical grade silicone to produce breast implants, in violation of the approval that had been issued by the notified body. Furthermore, a BBC investigation revealed that hundreds of thousands of individuals across the world could have been exposed to dangerously high levels of toxic metals from failing hip implants.

These revelations were some of the reasons why the European Commission issued, on 26 September 2012, two new regulation proposals to replace the three existing medical devices directives. One of the proposed regulations concerned *in vitro* diagnostic medical devices only, while the other one related to all other sorts of medical devices. These proposals marked the beginning of a long legislative process that led to the renewal of the regulatory framework on medical devices.

On 5 April 2017, the regulation on medical devices (hereinafter "MDR") and the regulation on *in vitro* diagnostic medical devices (hereinafter "IVDR") were adopted. They were published on 5 May 2017 and entered into force on 25 May 2017. The MDR will apply from 26 May 2020 and the IVDR from 26 May 2022.

In a nutshell, the highly anticipated texts address the concerns over the assessment of product safety and performance by placing stricter requirements on clinical evaluation and post-market clinical follow-up and by requiring better traceability of devices through the supply chain.

BRIEF OVERVIEW OF THE MAIN CHANGES

- ### SCOPE EXTENSION

Besides some changes in several definitions contained in the directives (including the definition of medical device itself), some products without an intended medical purpose and thus excluded from the previous regulatory framework, but which present the same characteristics and risk profile as analogous medical devices, have been included within the scope of the MDR.

These products, which are listed in annex XVI of the MDR, include, *inter alia*, contact lenses, facial or other dermal or mucous membrane fillers, equipment for liposuction, lasers and intense pulsed light

equipment for skin resurfacing, tattoo removal or hair removal, and equipment for electromagnetic brain stimulation.

Moreover, it has been clarified that software specifically intended by the manufacturer to be used for a medical purpose qualifies as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for lifestyle and well-being purposes, is not a medical device. It has also been clarified that the qualification of software, either as a medical device or an accessory for a medical device, will be independent of the software's location or the type of interconnection between the software and a device.

With regards to *in vitro* diagnostic medical devices, genetic tests and other tests that provide information about a patient's predisposition to a specific medical condition or disease, as well as tests that provide information to predict treatment response or reactions, such as companion diagnostics, have been included within the scope of the IVDR.

In order to ensure consistent qualification decisions across all Member States, in particular with respect to borderline cases, the Commission will have the right to decide, on its own initiative or at the duly substantiated request of a Member State, after having consulted the Medical Device Coordination Group, whether or not a specific product, category or group of products falls within the scope of the regulations.

- **INCREASED IDENTIFICATION AND TRACEABILITY OF DEVICES**

The regulations seek to ensure proper identification of all economic operators to whom devices are supplied or from whom devices are purchased. Devices will have a Unique Device Identifier (UDI) to provide for traceability throughout the supply chain to the end user or patient, allowing fast and effective measures in case of safety problems.

Before placing a device on the market, the manufacturer will have to assign a UDI to the device and provide it to the UDI database together with other core data elements related to that device. The UDI database will be available to the public via the European database on medical devices (Eudamed). The obligation to place the UDI on the label of the device will vary from one to five years after the date of application of the regulation, depending on the class of the device concerned.

Moreover, a summary of safety and clinical performance of high-risk devices written in a way that is clear to the intended user will be publicly available via Eudamed. The draft of this summary will have to be submitted to and validated by the notified body involved in the conformity assessment of the device concerned. Additional information will also need to be provided by the manufacturers of implantable devices, in particular via an implant card.

- **SAFETY AND PERFORMANCE REQUIREMENTS**

As regards safety and performance, the "essential requirements" established by the current directives will be replaced by the general safety and performance requirements described in Annex I of each regulation. Accordingly, manufacturers will have to perform a gap analysis of the consequences of the changed requirements for recertification of their existing devices.

- **MODIFIED RULES ON CLASSIFICATION AND CONFORMITY ASSESSMENT**

The changes to the classification rules, especially concerning *in vitro* diagnostic medical devices, will have to be sifted through by manufacturers as they will lead to reclassification (and hence additional requirements) for certain devices. Under the new rules, most *in vitro* diagnostic medical devices will have to be checked by a notified body.

As regards conformity assessment, increased control of high-risk devices will be performed. The MDR foresees that, subject to some exceptions, notified bodies will be obliged to request expert panels to scrutinise their clinical evaluation assessment reports concerning class III implantable devices and class IIb active devices intended to administer and/or remove a medicinal product. The notified bodies will have to give due consideration to the views expressed by these expert panels before granting any certificate. They will also have to notify the competent authorities of all certificates they grant for such high-risk devices, to allow said authorities and the Commission to apply further procedures or to take appropriate measures in case they have reasonable concerns. The IVDR provides for similar notification obligations with regard to class D *in vitro* diagnostic medical devices.

The requirements applicable to the designation of notified bodies have also been strengthened. Notified bodies will amongst others need to demonstrate they have permanent availability of sufficient administrative, technical and scientific personnel as well as personnel with relevant clinical expertise.

- **RISK MANAGEMENT SYSTEM**

Manufacturers will be obliged to implement a risk management system for each medical device. Risk management is defined by the regulations as a continuous iterative process throughout the entire life cycle of a device, requiring regular systematic updating. In carrying out risk management, manufacturers shall, in particular, establish and document a risk management plan for each device. They will have to identify and analyse the known and foreseeable hazards associated with each device. They will also have to estimate, evaluate and control the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse.

- **MORE STRINGENT REQUIREMENTS REGARDING CLINICAL EVIDENCE AND AVAILABILITY OF DATA REPORTS**

The regulations require manufacturers to conduct clinical or performance evaluations and to provide an appropriate level of clinical evidence given the characteristics of the device and its intended purpose. Subject to some exceptions, clinical evaluation needs to be based on clinical investigations in the case of implantable devices and class III devices. Clinical investigations also have to be performed for products without an intended medical purpose as listed in Annex XVI, unless reliance on existing clinical data from an analogous medical device is duly justified.

As regards in vitro diagnostic medical devices, clinical performance studies will have to be carried out, unless it is duly justified to rely on other sources of clinical performance data.

In any case, manufacturers will also be required to update the clinical or performance evaluations of their devices based on post-market clinical data collected throughout the life cycle of said devices.

- **INCREASED LIABILITY OF AUTHORISED REPRESENTATIVES**

Given the pivotal role of authorised representatives in ensuring the compliance of the devices produced by manufacturers who are not established in the EU and in serving as their contact person in the EU, the liability of these authorised representatives will increase. In particular, they will be legally liable for defective devices if a manufacturer established outside the EU has not complied with its obligations. This liability of authorised representatives will be without prejudice to the provisions of Directive 85/374/EEC concerning liability for defective products. Accordingly, the authorised representatives will be jointly and severally liable with the importers and manufacturers. Distributor and importers will also be subject to additional obligations, including a compliance check of their immediate upstream economic actor with the MDR or IVDR.

- **REPROCESSING AND FURTHER USE OF SINGLE-USE DEVICES**

Some specific rules applicable to the reprocessing and further use of single-use devices have been included in the MDR. However, such reprocessing and further use will need to be permitted by national law, and Member States are allowed to introduce national provisions that are stricter than those laid down in the MDR.

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